Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of pushing with breathing techniques on perineal statue and delivery outcome in nulliparous in Kamali hospital in Karaj

Protocol summary

Summary

This study is a randomized controlled clinical trial that was done in Kamali hospital in Karaj with the participation of 166 nulliparous women in 40-37 weeks of pregnancy who were candidates for vaginal delivery. The samples were randomly divided into two groups, using breathing techniques and routine maneuver (Valsalva maneuver).In control group pushing was done with keeping breath. In the breathing technique The mother was asked with the onset of abdominal pain to inhale two deep abdominal breaths and then exhale with open mouth. During controlled exhale ,they are asked to push for 5-4 seconds and then start the next push again according to the training instruction. In intervention group, pushing continued until crowning stage. After that, mothers were asked to control pushing by using blowing technique until ejection of the neonate head occurred .this process must be carry out only with uterine contractions, without increased abdominal pressure caused by moms excessive pushing. IN routine group, Valsalva maneuver continue until fetal scalp got out. Outcomes of this study include perineal status check, length of second stage of labor, fetal heart condition and the Apgar score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092819310N1**
Registration date: **2014-10-18, 1393/07/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-18, 1393/07/26

Registrant information

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-09-19, 1393/06/28

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pushing with breathing techniques on perineal statue and delivery outcome in nulliparous in Kamali hospital in Karaj

Public title

Effect of pushing with breathing techniques on perineal statue and delivery outcome in nulliparous in Kamali hospital in Karaj

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : age 18-35; gestational age ≥37 weeks ; Were anticipating a vaginal birth (both normal

spontaneous or instrumental) ;normal BMI ;having 6 score or more in vaginal exam according to Brinks score Exclusion criteria :Did not wish to participate ;Had an epidural analgesia ;emergency Cesarean ;fetal birth weight> 3999 gr or<2500 ; head circumference <32cm or>38cm

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **166**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti university

Street address
Nursing Midwifery Collage; Niayes; Valiaasr AV; Tehran

City
Tehran

Postal code
1985717443

Approval date
2013-09-14, 1392/06/23

Ethics committee reference number
400/4013

Health conditions studied

1

Description of health condition studied
delivery

ICD-10 code
O80.0

ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
perineal outcome

Timepoint
as soon as ending delivery

Method of measurement
according to definition of perineal damage

2

Description
apgar

Timepoint
as soon as ending of delivery

Method of measurement
accorging to apgar definition

3

Description
length of second stage of labor

Timepoint
at the end of intervention befor delivery

Method of measurement
hour(minute)

4

Description
abnormal FHR sound

Timepoint
during intervention every 5 minuts

Method of measurement
sony keyd

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group used breathing techniques from completing dilatation until fetus exit this means that with every contraction every muscle in their body starting to relax, by breathing deeply through the nose and blowing abdomen simultaneously .then while the abdominal muscles are contracted, they carry out a deep breath through half open mouth or through nose .after that they take a deep breath again and expiration with all strength over half-open mouth during 5-4 seconds and then after re breathing ,the next force will be started until the contraction ends. At the end of the contraction, two deep abdominal breathing was done (with an open glottis). This trend continued until the head of neonate is going to exit. At this time people took a deep breath and start to blow for 3-2 seconds .

Category

Prevention

2

Description
In control subjects using Valsalva maneuver for pushing in the second stage. This means that initially took a deep breath and hold it for 10 seconds and proceed with straining to have a closed glottis
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali hospital
Full name of responsible person
Mrs Tahlavi
Street address
Kamali AV, Karaj Alborz
City
Karaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ali Ziaee
Street address
MedicalCollage,Kudakyar AV,Evin,Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty